(b) a second facilitator substance to aid in the infusion of the first substance into said at least one cell whose concentration is greater than 20% of the total composition,

B1 cont. cl cont.

wherein the concentrations of said first and second substances are effective to stabilize the structure and nucleic acids of said at least one call, and further wherein the combined concentration of said first and second substances is [greater than 30%] 100% of said composition.

REMARKS

Claims 1-4, 6-8, 10 and 12-17 are in the present application.

Claims 1-17 have been rejected under 35 U.S.C.§112, first paragraph as allegedly containing new matter not described in the specification. Applicants have amended Claim 1 in order to further clarify the subject matter of the present invention by adding the phrase "whose concentration is less than 80% of the total composition in (a) [describing the first substance]; adding the phrase "whose concentration is greater than 20% of the total composition in (b) [describing the second substance], and amending the combined concentration of the first and second substances from "greater than 30%" to "100%" of said composition. Applicants have also cancelled Claims 5, 9 and 11. Accordingly, withdrawal of the instant rejection is respectfully requested.

Claims 1-17 have been rejected under 35 U.S.C. §112, first paragraph as allegedly containing subject matter not sufficiently described in the specification. Applicants respectfully submit that this rejection is incorrect. The cell types are described in Example 13 of the Specification at page 24 in full detail. In addition, Example 13 in the specification demonstrates two things: first, cells other than just microbial cells can be "stabilized", and the present invention does not have to be limited to cells in vaginal fluid as the cells used in Example 13 were not in that "medium". Accordingly, withdrawal of this rejection is respectfully requested.

Claims 1-5, 9 and 16 have been rejected under 35 U.S.C. §102(b) as allegedly anticipated by Dent et al.

The present invention describes a composition for stabilizing the structure and nucleic acids of at least one cell, said composition being comprised of:

(a) a first substance capable of precipitating or denaturing proteins, comprising at least one alcohol or ketone whose concentration is less than 80% of the total composition; and

(b) a second facilitator substance to aid in the infusion of the first substance into said at least one cell whose concentration is greater than 20% of the total composition, wherein the concentrations of said first and second substances are effective to stabilize the structure and nucleic acids of said at least one cell, and further, wherein the combined concentrations of said first and second substances is 100% of said composition.

Dent et al. do not teach, disclose or anticipate the present invention as claimed. Dent et al. only teach stabilization of protein structures in cells, and only in Xenopus embryo cells at that. There is no mention or discussion of nucleic acids, including DNA, RNA, or ribosomal RNA in Dent et al. Also, Dent et al. is limited to a very specific formulation for the fixative used: 80% methanol/20% DMSO. Dent et al. also uses a fixing time period of 2-12 hours, which differs from 1-4 days in the present invention.

Although the claims have been rejected as anticipated under 35 U.S.C.§102(b) on the disclosure of Dent et al., it is axiomatic that anticipation under Section 102 requires that the prior art reference disclose every element of the claim. In re King, 801 F.2d 1324, 1326, 231 U.S.P.Q. 136, 138 (Fed. Cir. 1986). Thus there must be no differences between the subject matter of the claim and the disclosure of the prior art reference. Stated in another way, the reference must contain within its four corners adequate directions to practice the invention. The corollary of this rule is equally applicable. The absence from the reference of any claimed element negates anticipation. Kloster Speedsteel AB v. Crucible Inc., 793 F.2d 1565, 1571, 230 U.S.P.Q. 81, 84 (Fed. Cir. 1986).

Here it is clear that Claim 1 as amended and all claims dependent thereon differ from Dent et al. Clearly, Kloster Speedsteel shows that Dent et al. falls far short of the statutory standard of 35 U.S.C. 102(b). Claim 1 and all claims dependent thereon are not anticipated by Dent et al. Withdrawal of the instant rejection under Section 102 is therefore respectfully requested.

The Examiner has alleged that Claims 6-8, 10, 12 –15 and 17 are rendered obvious under 35 U.S.C. §103 by Dent et al. and further in view of Bresser et al. Applicants note that the rejection of Claim 11 under Section 103 is rendered moot by the cancellation of Claim 11.

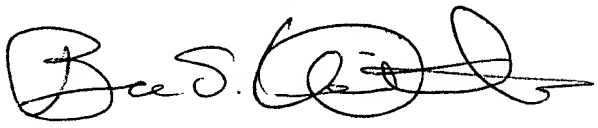
Neither of the above references, singly nor in combination teach or suggest the claimed invention. As stated above, Dent et al. only disclose stabilization of protein structures in cells and there is no disclosure therein regarding stabilization of nucleic acids.

Bresser et al. is even more limiting. It teaches rather low concentrations of the active components (2-20% DMSO, 2-20% alcohol, etc. see col. 2, ln 50-65). As was previously pointed out to the Examiner, in the previous Amendment, Bresser et al. clearly teaches away from the claimed invention.

Even the combination of Dent et al. and Bresser et al. clearly teaches away from the claimed invention. Withdrawal of the present rejection under Section 103 is therefore respectfully requested.

In view of the above Amendments and Remarks, Applicants believe that the present application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,



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